September 15, 2021

Possis Medical, Inc.
Frank Freedman
Senior Regulatory Affairs Associate
9055 Evergreen Blvd., N.w.
Coon Rapids, Minnesota 55433-8003

Re: K062172
Trade/Device Name: Fetch Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Frank Freedman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 20, 2006. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 09:20:47 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2006

Possis Medical, Inc.
c/o Frank B. Freedman, Ph.D.
Senior Regulatory Affairs Associate
9055 Evergreen Boulevard NW
Minneapolis, MN 55433-8003

Re: K062172
Trade/Device Name: FETCH Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II
Product Code: DXE
Dated: September 7, 2006
Received: September 8, 2006

Dear Dr. Freedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062172

Device Name: FETCH Aspiration Catheter

Indications For Use: The FETCH™ Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from 2 mm or larger vessels in the arterial system.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Donna R. Vochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062172

Appendix 3

5. 510(k) Summary

SEP 2 0 2006

Device Common Name: Embolectomy Catheter

Device Trade Name: FETCH™ Aspiration Catheter

Device Classification/Name: Class II 21CFR 870.5150
Embolectomy Catheter
Product Code, DXE

Manufacturer:
Possis Medical, Inc.
9055 Evergreen Boulevard, N.W.
Coon Rapids, MN 55433
Phone: 763.717.1013 Fax: 763.780.2227

Establishment Registration: 2183460

Submitter: Frank B. Freedman

Contact Person:

Primary Contact	Secondary Contact
Frank B. Freedman	Mark D. Stenoien
Possis Medical, Inc.	Possis Medical, Inc.

Performance Standards: No performance standards have been developed under Section 514 for this device.

Predicate Devices: Pronto Extraction Catheter (K042937) and other embolectomy catheters

Device Description
The FETCH Aspiration Catheter is a rapid exchange, low-profile tip, dual lumen catheter that uses a 0.014" (0.36 mm) guide wire to track to the target site. It is used for aspiration of fresh, soft emboli and thrombi. Its outer diameter 0.052" (1.33 mm) or 4F allows advancement to the target site through a 6F (0.070" I.D.) guiding catheter. A radiopaque marker is located about 2 mm from the distal tip. FETCH is provided with an extension line, 30 cc syringe, one-way stopcock and a 40 micron collection basket. This basket can be used to filter aspirated blood for laboratory analysis of collected thrombus.

Indications for Use
The FETCH™ Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Supporting Information
Bench, biocompatibility, animal, packaging and sterilization testing supported the substantial equivalency of the FETCH Aspiration Catheter.

Conclusion
FETCH is substantially equivalent to the Pronto Extraction Catheter and other embolectomy catheters.